

**UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION**

HEATHER LECCE, et al.,	)	CASE NO. 1:18CV2720
	)	
PLAINTIFFS,	)	JUDGE SARA LIOI
	)	
v.	)	
	)	<b>MEMORANDUM OPINION AND</b>
	)	<b>ORDER</b>
MEDTRONIC, INC., et al.,	)	
	)	
DEFENDANTS.	)	

Before the Court is the motion of plaintiffs Heather and Anthony Lecce to remand this case to the Richland County Court of Common Pleas. (Doc. No. 8 [“Mot.”].) Defendants Medtronic, Inc. and Medtronic USA, Inc. filed a brief in opposition (Doc. No. 12 [“Opp’n”]) and plaintiffs filed a reply (Doc. No. 13 [“Reply”]). For the reasons discussed herein, plaintiffs’ motion for remand is GRANTED.

**I. BACKGROUND**

On October 18, 2017, plaintiff Heather Lecce (“Heather”) received care, including but not limited to the interrogation of her pacemaker, by defendant Nationwide Children’s Hospital’s agents, servants, and/or employees, and defendants Medtronic, Inc.’s and Medtronic USA, Inc.’s (collectively, “Medtronic”) agents, servants and/or employees in a hospital owned and operated by defendant Medcentral Health Systems d/b/a OhioHealth Mansfield Hospital. (Doc. No. 1-1, Complaint [“Compl.”] ¶ 11.) Immediately following her provided care, Heather experienced complications with her Medtronic pacemaker. (*Id.* ¶ 12.)

On October 17, 2018, Heather and her husband plaintiff Anthony Lecce (“Anthony”) filed the instant action in the Richland County Court of Common Pleas. Plaintiffs’ complaint alleges four claims for relief: (1) medical malpractice, (2) negligence, (3) products liability, and (4) loss of consortium. On November 23, 2018, Medtronic removed this action to this Court. (Doc. No. 1 [“Not.”].) On November 30, 2018, plaintiffs filed the present motion to remand. This issue is now ripe for the Court’s review.

## **II. STANDARD OF REVIEW**

Under 28 U.S.C. § 1441(a), defendants may remove a civil action from a state court only when the federal court has original jurisdiction over the claims alleged in the state court complaint. “The party seeking removal bears the burden of demonstrating that the district court has original jurisdiction.” *Eastman v. Marine Mech. Corp.*, 438 F.3d 544, 549 (6th Cir. 2006). “[B]ecause lack of jurisdiction would make any decree in the case void and the continuation of the litigation in federal court futile, the removal statute should be strictly construed and all doubts resolved in favor of remand.” *Id.* at 549–50 (quoting *Brown v. Francis*, 75 F.3d 860, 864–65 (3d Cir. 1996)).

A federal court has original federal-question jurisdiction in “all civil actions arising under the Constitution, laws, or treaties of the United States.” 28 U.S.C. § 1331. An action “arises under” federal law if: (1) “federal law creates the cause of action[,]” or (2) “the vindication of a right under state law necessarily turned on some construction of federal law.” *Merrell Dow Pharm. Inc. v. Thompson*, 478 U.S. 804, 808–09, 106 S. Ct. 3229, 92 L. Ed. 2d 650 (1986) (quoting *Franchise Tax Bd. v. Constr. Laborers Vacation Tr.*, 463 U.S. 1, 9, 103 S. Ct. 2841, 77 L. Ed. 2d 420 (1983)).

Generally, the plaintiff is the master of his or her own complaint and federal jurisdiction must be apparent “on the face” of the “properly pleaded complaint.” *Caterpillar Inc. v. Williams*, 482 U.S. 386, 392, 107 S. Ct. 2425, 96 L. Ed. 2d 318 (1987). The “mere presence of a federal issue

in a state cause of action does not automatically confer federal-question jurisdiction.” *Merrell Dow*, 478 U.S. at 813.

However, even when a claim originates in state law, the Supreme Court has recognized that “in certain cases federal-question jurisdiction will lie over state-law claims that implicate significant federal issues.” *Grable & Sons Metal Prods., Inc. v. Darue Eng’g & Mfg.*, 545 U.S. 308, 312, 125 S. Ct. 2363, 162 L. Ed. 2d 257 (2005). “The doctrine captures the commonsense notion that a federal court ought to be able to hear claims recognized under state law that nonetheless turn on substantial questions of federal law, and thus justify resort to the experience, solicitude, and hope of uniformity that a federal forum offers on federal issues[.]” *Grable*, 545 U.S. at 312.

The removing party bears the burden of establishing that federal-question jurisdiction exists. *Long v. Bando Mfg. of Am., Inc.*, 201 F.3d 754, 757 (6th Cir. 2000). “All doubts as to the propriety of removal are resolved in favor of remand.” *Coyne v. Am. Tobacco Co.*, 183 F.3d 488, 493 (6th Cir. 1999).

### **III. ANALYSIS**

Medtronic contends that the Court possesses federal-question jurisdiction over this case because plaintiffs’ claims stem from alleged complications and negligent care of Heather’s pacemaker, which is categorized as a Class III medical device under the Federal Food, Drug and Cosmetic Act (“FDCA”), subject to the most rigorous review by the U.S. Food and Drug Administration (“FDA”). Specifically, Medtronic contends that federal-question jurisdiction lies over plaintiffs’ state-law claims because plaintiffs’ claims will require the Court to “second-guess the design, manufacturing, and programming of this Class III medical device,” and the Court’s decision “necessarily will ‘implicate significant federal issues’ and ‘turn on substantial questions

of federal law.’” (Not. ¶ 18 (citing *Grable*, 545 U.S. at 312).) Alternatively, Medtronic contends there is a substantial federal question in this case because the Medical Device Amendments of 1976 (“MDA”) to the FDCA “expressly preempts any state-law claim that would impose a requirement that is ‘different from, or in addition to’ those imposed by the FDA.” (Not. ¶ 14; Opp’n at 85.<sup>1</sup>)

### **A. Substantial Federal-Question Doctrine**

Under the substantial federal-question doctrine, federal-question jurisdiction will lie over state-law claims if a federal issue is (1) necessarily raised, (2) actually disputed, (3) substantial, and (4) capable of resolution in federal court without disrupting the federal-state balance approved by Congress. *Gunn*, 256 U.S. at 258 (citing *Grable*, 545 U.S. at 313–14). Here, the first two factors are not disputed. Plaintiffs’ claims include a federal issue—the FDA-approved Class III pacemaker—and the negligent interrogation and performance of that pacemaker is in dispute. (Compl. ¶¶ 12, 17, 20–31; Not. ¶ 10.) Instead, the parties disagree as to whether the federal issue is “substantial” and whether removal disrupts Congress’s intended federal-state court balance.

#### **1. Substantial**

In considering whether the federal issue is “substantial,” the Court must consider “the importance of the issue to the federal system as a whole.” *Gunn*, 568 U.S. at 260. In *Gunn*, the Court determined that there was no substantial federal question at issue because the state court’s resolution would have no bearing on any federal law, nor would it impact any government action. *Id.* at 261–62.

[I]t is not enough that the federal issue be significant to the particular parties in the immediate suit; that will *always* be true when the state claim “necessarily raise[s]” a disputed federal issue, as *Grable* separately requires. The substantiality inquiry

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<sup>1</sup> All page number references are to the page identification number generated by the Court’s electronic docketing system.

under *Grable* looks instead to the importance of the issue to the federal system as a whole.

*Id.* at 260.

In reaching its decision, the Court in *Gunn* compared the Court’s previous decisions in both *Grable* and *Smith v. Kansas City Title & Trust Co.*, 225 U.S. 180, 41 S. Ct. 243, 65 L. Ed. 577 (1921). In *Grable*, the Court found that the substantial federal-question doctrine supported removal. In *Grable*, the Internal Revenue Service (“IRS”) seized the plaintiff’s property to satisfy the plaintiff’s federal-tax delinquency. *Grable*, 545 U.S. at 310–11. The plaintiff later filed a state law quiet title action against the third-party buyer, claiming that the sale was invalid because the IRS failed to comply with certain federally imposed notice requirements. *Id.* In determining that removal was proper because of the substantial federal question, the Court emphasized the federal government’s “strong interest” in being able to recover delinquent taxes through property seizures and ensuring they act properly in the process. *Id.* at 315.

In its decision, the Court in *Grable* called *Smith* the “classic example” of a state claim arising under federal law. *Grable*, 545 U.S. at 312. In *Smith*, the plaintiff argued that defendant bank could not purchase certain bonds issued by the federal government because the federal government had acted unconstitutionally in issuing the bonds. *Smith*, 255 U.S. at 195–96. The Court found this raised a substantial federal question because again, like in *Grable*, “the relevant point was not the importance of the question to the parties alone,” but rather the relevant point was the importance more generally of a determination that the government might have acted under an unconstitutional law. *Gunn*, 568 U.S. at 261 (citing *Smith*, 255 U.S. at 201).

Here, like in *Gunn*, there is no substantial federal issue. In both *Grable* and *Smith*, the disputed federal issue directly involved a government law or action by the government. More

plainly, there was a substantial federal question because the courts had to determine whether the government acted properly or constitutionally.

Here, the state court will not have to determine whether any government action was proper or constitutional. Instead, the court will determine only how federal law affects the parties in this case. The court's decision will have no bearing on federal law or federal government action. The resolution of this case has virtually no importance to the federal system as a whole.

This Court's decision is only reinforced by another recent decision in this district. *See Steed v Bos. Sci. Corp.*, Case No. 4:17CV0824, 2017 WL 2984854 (N.D. Ohio July 12, 2017). Although not binding precedent, this Court agrees with the reasoning in *Steed*.

The facts in *Steed* were almost identical to the present case. In *Steed*, the plaintiff underwent a surgical proceeding involving an FDA-approved Class III medical device. *Id.* at \*1. After complications, the plaintiff brought products liability and medical malpractice claims against the health-care providers and the medical device's manufacturer. *Id.* Defendants then attempted to remove the case to federal court on the basis of federal-question jurisdiction. *Id.* Defendants contended there was federal-question jurisdiction because plaintiffs' claims were "controlled and preempted by the [FDA's approval] process for a Class III medical device." *Id.*

In considering whether the presented federal issue was "substantial" the court noted:

The Sixth Circuit has not considered the issue in the context of FDA-regulated products since the Supreme Court's ruling in *Gunn*. But, post-*Gunn*, the majority of federal courts considering the issue have remanded these actions and held that state tort claims concerning FDA-regulated products do not raise a substantial federal issue[.]

*Id.* at \*3 (footnote omitted) (citing cases).<sup>2</sup> Relying on *Gunn*, the court held: “While the federal question at issue in the present case is significant to the parties, it does not transcend the parties, affect the government’s operations, or challenge federal law in a manner evidencing importance of the issue to the federal system as a whole.” *Id.* at \*4.

## **2. Federal-State Court Balance**

Moreover, allowing federal-question jurisdiction in this case would disrupt Congress’s intended federal-state court balance. The Supreme Court in *Merrell Dow* found the lack of a private right of action for federal misbranding laws indicated Congress’s intent to allow such actions in state courts. *Merrell Dow*, 478 U.S. at 812 (“We think it would similarly flout, or at least undermine, congressional intent to conclude that the federal courts might nevertheless exercise federal-question jurisdiction and provide remedies for violations of that federal statute solely because the violation of the federal statute is said to be a ‘rebuttable presumption’ or a ‘proximate cause’ under state law, rather than a federal action under federal law.”) The Court in *Merrell Dow* found it improbable that Congress intended to disrupt the federal-state court balance by allowing federal-question jurisdiction over state-law actions simply because they are premised on federal labeling standards. *Grable*, 545 U.S. at 318 (discussing *Merrell Dow*) (“For if the federal labeling standard without a federal cause of action could get a state claim into federal court, so could any

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<sup>2</sup> The Sixth Circuit has not addressed the substantial federal-question doctrine after *Gunn*. However, in *Mikulski v. Centerior Energy Corp.*, 501 F.3d 555 (6th Cir. 2007), the Sixth Circuit addressed the substantially factor from *Grable* with a four-factor test:

- (1) whether the case includes a federal agency, and particularly, whether that agency’s compliance with the federal statute is in dispute; (2) whether the federal question is important (i.e., not trivial); (3) whether a decision on the federal question will resolve the case (i.e., the federal question is not merely incidental to the outcome); and (4) whether a decision as to the federal question will control numerous other cases (i.e., the issue is not anomalous or isolated).

*Mikulski*, 501 F.3d at 570 (finding no one factor dispositive and rather the factors must be considered collectively). Even under this test, the Court finds the federal issue in this case is not substantial.

other federal standard without a federal cause of action. And that would have meant a tremendous number of cases.”).

The Court in *Grable* narrowed *Merrell Dow*’s holding and found the lack of a private right of action does not preclude federal-question jurisdiction where there is a substantial federal issue, but nevertheless reemphasized that the lack of a private right of action is strong evidence that Congress intended to allow state court actions. *Grable*, 545 U.S. at 317–20. “While the lack of a private right of action does not by itself preclude federal jurisdiction, the combination of its absence and the absence of preemption is ‘an important clue to Congress’ s conception of the scope of the jurisdiction to be exercised under 1331.’” *Steed*, 2017 WL 2984854, at \*4 (quoting *Grable*, 545 U.S. at 318). Further, the Court in *Grable* suggested that finding federal-question jurisdiction where Congress did not include a private federal right of action should only be in “rare” cases where extending jurisdiction will not “materially affect, or threaten to affect, the normal currents of litigation.” *Grable*, 545 U.S. at 319.

Here, Congress did not include any private right of action in the FDCA. *See Merrell Dow*, 478 U.S. at 806–07 (“[T]he FDCA does not create or imply a private right of action for individuals injured as a result of violations of the Act[.]”). Moreover, Congress allowed state courts’ awards for damages of violations of FDA requirements. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330, 128 S. Ct. 999, 169 L. Ed. 2d 892 (2008). And, there is also at least an open question as to whether state regulations may parallel the FDA’s requirements under the FDCA. *Id.*

Lastly, finding federal-question jurisdiction simply because the action involves a Class III medical device would open federal courts’ doors to any medical malpractice case involving an FDA-approved medical device. These cases are not rare and would materially affect the normal currents of litigation.



For these reasons, the Court finds that allowing federal-question jurisdiction in this case would disrupt Congress's intended federal-state court balance.

#### **B. Federal Preemption of State-law Claims**

Medtronic also argues that removal is proper in this case because Section 360k of the MDA expressly preempts any state-law claim that would impose a requirement that is “different from, or in addition to” those imposed by the FDA. However, it is well settled that removal cannot be based on a defense. *Caterpillar Inc.*, 482 U.S. at 392–93 (“[I]t is now settled law that a case may *not* be removed to federal court on the basis of a federal defense, including the defense of preemption, even if the defense is anticipated in the plaintiff's complaint[.]”). It is similarly well settled that federal preemption over a state-law claim is a defense. *Id.* at 393. Therefore, to the extent that the MDA preempts any state common law claims raised by plaintiffs, this is not a proper basis for removal.<sup>3</sup>

#### **IV. CONCLUSION**

As this Court lacks subject-matter jurisdiction over the plaintiffs' claims, plaintiffs' motion to remand is GRANTED. This case is remanded to the Richland County Court of Common Pleas.

**IT IS SO ORDERED.**

Dated: July 8, 2019

  
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**HONORABLE SARA LIOI**  
**UNITED STATES DISTRICT JUDGE**

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<sup>3</sup> There is an exception that does allow the Court to extend federal-question jurisdiction over a case on the basis of preemption: the complete-preemption doctrine. “If Congress intends that a federal statute should completely preempt an area of state law, any complaint alleging claims under that area of state law is presumed to allege a claim arising under federal law.” *Gentek Bldg. Prods., Inc. v. Sherwin-Williams Co.*, 491 F.3d 320, 325 (6th Cir. 2007). The complete preemption doctrine does not apply here because, by allowing state courts' awards for damages and state-law claims that parallel the FDCA requirements, it is clear Congress did not intend complete preemption.